UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re:	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	Subcategory No. 06-11337
	)	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO:	)	
United States ex rel Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation Civil Action No. 09-CV-10547	)	
United States ex rel Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation Civil Action No. 00-10698	)	

RELATOR VEN-A-CARE'S REPLY TO MEMORANDA OF LAW IN OPPOSITION TO SETTLEMENT BETWEEN VEN-A-CARE , CALIFORNIA, FLORIDA AND SCHERING/WARRICK

The Relator, Ven-A-Care of the Florida Keys, Inc. ("VEN-A-CARE"), replies to the objections to its proposed Settlement with Schering/Warrick advanced by the United States, the New York City/Counties and various states (collectively referred to as "the Objectors").[1]

[1] VEN-A-CARE joins with Schering/Warrick in seeking approval of the Settlement. However, as set forth in their Joint Memorandum, and as one would expect, there are several areas in which Schering and VEN-A-CARE are not in agreement, such as with respect to "government knowledge" issues and the relevance of the FUL formula set forth in DRA 2005. Accordingly, VEN-A-CARE does not join in Schering/Warrick's Reply; however, these differences should not impede a resolution of this case.

Introduction

Notwithstanding misguided assertions by the Objectors, the Settlement is fair, adequate and reasonable; it will not prevent the states from recovering additional sums; and it is entirely consistent with the strategy the Department of Justice has told this Court it is following in declining to intervene in approximately 10 VEN-A-CARE AWP qui tam actions pending before this Court. The Settlement will also enable VEN-A-CARE and its counsel team to effectively direct their multi-million dollar annual investment of professional time, expenses and litigation costs to AWP cases still in dispute, to maximize recoveries for the taxpayer.

VEN-A-CARE and its counsel pioneered what is now known as the "AWP type action" and have pursued those cases relentlessly for more than 14 years. It is because of VEN-A-CARE's efforts that there are AWP cases and settlements such as the present one. It is also worth noting that throughout VEN-A-CARE's long history as a qui tam relator, it has never found itself before any court at odds with the United States or any state Attorney General. Instead, it conformed its litigation strategy to that of its government partners, worked diligently to develop, lead, fund and staff joint trial teams to secure favorable recoveries for the taxpayer, and resolved amicably any questions of awards, fees and costs. It is VEN-A-CARE's sincere hope that the Court will carefully evaluate the Settlement, make the determinations requested by the Settling Parties and then permit and request that the United States make a consent determination informed by the Court's determinations about the Schering Brand and state action preclusion issues.[2]

VEN-A-CARE's Position

[2] In this regard, VEN-A-CARE has filed, as **Exhibit A** to this Reply, the *Allocation Agreement*, which provides that the parties request the Court to make appropriate determinations as to the Settlement's effect on CMS's recovery of amounts from Florida and California only.

1. VEN-A-CARE Agrees that the Attorney General can Withhold Consent to Dismissal; However, if the Attorney General Does So, He Should Intervene and Lead this Case or Inform the Court and the Parties that He Prefers to Pursue Recovery Via the Alternate Remedy of State Actions.

VEN-A-CARE has never disputed the right of the United States Attorney General to withhold consent to a dismissal of an False Claims Act ("FCA") qui tam action in which the government has declined to intervene. While this position may be contrary to that of other relators, VEN-A-CARE believes the Attorney General should and does possess such ultimate control over the agreed dismissal of any FCA qui tam action. That said, important matters remain for the Court to resolve in order to find whether the settlement is "fair, adequate and reasonable under all the circumstances." The Attorney General may still withhold his consent notwithstanding the Court's affirmative findings, but the statute gives him no right to block the relator's request for preliminary findings by the Court necessary to the negotiated disposition of the action.

If the Department of Justice remains opposed to the Settlement after the Court conducts its review and makes its findings, the government still has certain options that will avoid forcing the Court to continue to expend judicial resources on a case the parties want to settle. First, it can exercise its right to intervene for good cause pursuant to 31 U.S.C. § 3730(c)(3).[3] This option would seem most appropriate if the Department believes that the damages model applied by the VEN-A-CARE, California and Florida is insufficient.[4] The government's second option is

[3] 31 U.S.C.§ 3730(c)(3) provides in pertinent part as follows: "When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause."

[4] VEN-A-CARE is prepared to present to the Court the information it provided to the government over the years about the other Warrick drugs and about the Schering Brands if the Court or the United States believe that such a showing would help to resolve this matter.

simply to inform the Court and VEN-A-CARE that the Department of Justice believes it would be in the interest of the United States for VEN-A-CARE to stand down with respect to its U.S. FCA actions in which the government has declined to intervene, in particular by no longer pursuing its case against Schering/Warrick, and limit recoveries to those that arise from the state action alternative remedy. 31 U.S.C.§ 3730(c) (5).[5] In either event, VEN-A-CARE will continue to provide financial and litigation resources to the states and the United States in order to maximize taxpayer recoveries.[6]

2. A Relator-Only Dismissal Should Benefit, Not Prejudice, the Interests of the United States.

The Settlement Agreement states, and the Settling Parties have repeatedly made it clear, that the dismissal of this action is by VEN-A-CARE alone, and only in its capacity as a qui tam relator. As emphasized in the *Joint Motion for Approval of Settlement and Dismissal*, VEN-A-CARE took great care to ensure that the Settlement did not require the United States to join in the Settlement Agreement, the release *or the dismissal.* Accordingly, the dismissal could conceivably prejudice the United States only if the United States itself desired to pursue an FCA case against Schering regarding AWP. The Department of Justice has informed the Court that it

[5] 31 U.S.C.§ 3730(c)(5) provides in pertinent part as follows: "Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section."

[6] The Department of Justice has informed the Court that it declined to intervene in the remainder of VEN-A-CARE's Boston AWP FCA action because it prefers to allow the states to recover Medicaid damages and repay the United States pursuant to 42 USC § 1396. This is a strategy that VEN-A-CARE made possible by seeking leave of the Court to inform the states' attorneys general about the AWP fraud and pursue state law qui tam actions, and by then initiating, supporting and assisting the states in their efforts. If the Department of Justice truly believes that VEN-A-CARE's litigation strategy in the declined Boston actions is inconsistent with that of the Department, it simply needs to tell VEN-A-CARE that it prefers to pursue only its preferred alternative remedy and VEN-A-CARE will modify its role accordingly. This would include pursuing VEN-A-CARE's Florida and California state qui tam actions (including the necessary remaining discovery and motions practice) and assist the other (non-qui tam) states as appropriate.

has no such inclination, and that it declined to intervene in this action because it prefers to allow the states to pursue the Medicaid damages in question. It should be noted that this is precisely what Florida and California have done, with VEN-A-CARE's assistance. However, if the United States prefers to reverse this course, it should intervene and VEN-A-CARE and its counsel will continue to support and assist the Department as they have in other cases in which the government has intervened.

3. A Relator-Only Dismissal Need Not Bind or Prejudice Non-Party States.

This issue remains open for the court to resolve. VEN-A-CARE suggests the Court may wish to ascertain whether it is the Objectors' position that the Settlement will prejudice their ability to pursue their claims, regardless of how the Court views the effect of the Allocation Agreement and regardless of how the court ultimately decides the question of preclusion.

4. The Settlement's Provision for a Determination About Schering's Brand Drugs is Part and Parcel of an Analysis of the Fairness, Adequacy and Reasonableness of the Settlement, not a Request for an "Advisory Opinion."

In determining whether the settlement is fair, adequate and reasonable under all the circumstances, the Court will necessarily wish to be satisfied that all elements of potential recovery, including liability for Schering's brand drugs, have been taken into account and properly evaluated.

VEN-A-CARE discovered, disclosed and pleaded Schering/Warrick's AWP-related fraud in 1997, long before the term "AWP case" entered the lexicon of litigation. The requested findings about the Schering brand drugs are entirely consistent with VEN-A-CARE's allegations from the time it commenced its first qui tam action against Schering/Warrick and entirely consistent with the litigation strategy VEN-A-CARE has followed in its Texas, Florida,

California and United States cases to date. Further, VEN-A-CARE's Schering allegations are based on the theory that VEN-A-CARE has successfully advanced in its federal and state Medicaid AWP cases since 1995.

In a nutshell, VEN-A-CARE has alleged that drug manufacturers are on notice of the approximately 50 state Medicaid reimbursement formulas and that the formulas are intended to estimate actual acquisition costs based on the prices generally and currently paid in the marketplace. With limited exceptions, such as Texas, the state formulas in effect assume that the required "WAC plus" or "AWP minus" calculation will result in an ingredient cost amount consistent with prices generally and currently paid in the marketplace. Drug manufacturers that cause the reporting of prices substantially higher than prices generally and currently paid in the market place violate the FCA by causing the payment of inflated Medicaid reimbursement. Since a very large range of drug prices are paid by numerous customers in different classes of trade and at different times for tens of thousands of drugs, identifying the FCA violations requires access to industry insider prices and marketing conduct over time.

VEN-A-CARE discovered that certain brand and generic drug manufacturers were reporting inflated prices for certain of their drugs. Through FCA and related state court actions, VEN-A-CARE has caused the recovery of more than $300,000,000 with respect to the brand drugs alone.[7] In the case of Schering/Warrick, however, VEN-A-CARE's information showed that brand AWP prices were being reported generally within an expected 20% range of what VEN-A-CARE believed to be a truthful WAC. Accordingly, when the states' Medicaid reimbursement formulas applied Schering's reported prices, the resulting ingredient cost

[7] If the recoveries relating to all pharmaceutical products, brand, generic, nutritional and biological, and theories of liability are considered, the total recoveries that VEN-A-CARE has caused or contributed to are estimated to be well in excess of a billion dollars.

estimations were consistent with the prices generally and currently paid in the marketplace. In sharp contrast, Schering/Warrick caused price reports for the Warrick albuterol products to be inflated far above prices generally and currently paid in the marketplace. VEN-A-CARE has pointed to this dichotomous price reporting conduct as evidence that the company knew its generic price reports were false.[8]

Now, nearly 15 years after filing the first AWP type case, VEN-A-CARE seeks to consummate a settlement that is consistent with its allegations and litigation strategy against Schering. The Objectors seek to intercede because certain of the litigating states are pursuing AWP cases under alternative laws and litigation theories and strategies. VEN-A-CARE does not believe that these states should direct how VEN-A-CARE chooses to litigate its case any more than VEN-A-CARE should direct the states.

5. The Settlement Terms are Fair, Adequate and Reasonable.

The $55,000,000 proceeds from the Settlement of VEN-A-CARE's Florida and California cases will raise the total AWP Medicaid recoveries from Schering/Warrick to more than $125,000,000[9] and add substantially to the federal recovery. In light of these circumstances, the Settlement is entirely consistent with the Department's strategy of looking to the state actions to recover federal funds pursuant to 42 U.S.C. § 1396. As noted above, the full impact of the Settlement can only be ascertained after the Court determines whether a relator-only dismissal would relieve the remaining litigating states from any obligation to repay the federal share on any recoveries to the United States.

[9] It should be noted that, in addition to the recoveries set forth in the supporting Declaration of T. Mark Jones, VEN-A-CARE understands that the State of Alabama has now settled with Schering for an unpublished portion of a settlement with several defendants. Every state settlement that VEN-A-CARE has participated in has included protections insuring that the United States receives its share, as does the current Settlement.

6. If the Attorney General Continues to Withhold Consent to a Relator-Only Dismissal After Being Fully Informed of the Dismissal's Effect, VEN-A-CARE Asks the Court to Enter Appropriate Orders that Will Enable VEN-A-CARE to Conform its Litigation Strategy in the Declined Boston Cases to that of the Department of Justice.

Should the Attorney General continue to withhold consent to the Settlement after this Court has determined its effect, VEN-A-CARE respectfully requests that that the Court include, as a reason for its order disapproving the settlement, the goal espoused by the United States to recover the damages at issue through the alternative remedy presented by the state court actions It makes little sense for VEN-A-CARE to continue to pursue recoveries in the FCA cases in which the United States did not intervene if the Attorney General believes that VEN-A-CARE is working at cross purposes with the course preferred by the Department of Justice.

Dated: September 4, 2009

Respectfully submitted,

/s/ Alison W. Simon

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **RELATOR VEN-A-CARE'S REPLY TO MEMORANDUM OF LAW IN OPPOSITION TO SETTLEMENT BETWEEN VEN-A-CARE, CALIFORNIA, FLORIDA AND SCHERING/WARRICK** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Alison W. Simon
Alison W. Simon

Dated: September 4, 2009